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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,122	01/15/2002	John I. Shipp	115.0001-00000	9694

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EXAMINER

O CONNOR, CARY E

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,122

Applicant(s)

SHIPP ET AL

Examiner

Cary E. O'Connor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-94 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-57 and 61-72 is/are allowed.
- 6) ☒ Claim(s) ~~1-11, 15-26, 30-36, 38, 42, 45-50, 58, 59, 73-88, 93 and 94~~ ¹⁻²⁶ is/are rejected.
- 7) ☒ Claim(s) ~~12-14, 27-29, 37, 39-41, 43, 44, 60 and 89-92~~ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the cannula" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-7, 10, 15, 17, 87, 88 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Heidmueller (5,281,230). Heidmueller shows a surgical extractor comprising a body 10 having a leading end, a trailing end, a longitudinal axis and a lumen between the ends. The lumen includes a seal (column 4, lines 3-6) and a dilator (bowls 2, 3) is located at the leading end of the body and is movable between an unexpanded position and an expanded position. As to claim 5, the maximum cross-sectional dimension of the body is smaller than the expanded cross-sectional dimension of the dilator, as can be seen in Figure 1a. As to claims 6, 15 and 94, the extractor may be used to aspirate material from a body cavity (column 2, lines 22-24) via lumen 19. As to claims 7, 17 and 87, tissue, i.e. the gallbladder, may be grasped by the dilator in order to remove it from the body. As to claims 10 and 88, guiding tube 1 is considered a cannula and has a lumen for accepting the instrument.

Claims 1, 5, 6, 10, 26, 30, 33, 34, 77, 84-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (5,843,017). Yoon shows a surgical extractor comprising a body 26 having a leading end, a trailing end, a longitudinal axis and a lumen 50 between the ends. The lumen includes a seal (column 20, lines 18-20) and a dilator 28 is located at the leading end of the body and is movable between an unexpanded position and an expanded position. As to claim 5, the maximum cross-sectional dimension of the body is smaller than the expanded cross-sectional dimension of the dilator, as can be seen in Figure 6. As to claim 6, the instrument 20 may be used to aspirate material from a body cavity (column 10, lines 32-35). As to claims 10 and 30, outer tubular member 24 is considered a cannula. As to claim 26, the probe may be

used to grasp tissue (column 17, lines 15-16). As to claim 77, note the handles discussed in column 19, lines 44-65.

Claims 1, 5, 18-20 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kieturakis (5,643,282). Kieturakis shows a surgical extractor comprising a body having a leading end 14, a trailing end 11, a longitudinal axis and a lumen 20 between the ends. The lumen includes a seal 29 and a dilator 27 is located at the leading end of the body and is movable between an unexpanded position and an expanded position. As to claim 5, the maximum cross-sectional dimension of the body is smaller than the expanded cross-sectional dimension of the dilator, as can be seen in Figure 8C. As to claim 18, note that a cannula 50 is inserted into the body cavity (Fig. 8A) and the dilator is inserted through the cannula (Fig. 8B). The leading end of the dilator is expanded and a grasper 61 is inserted through the dilator (Fig. 8C). The tissue is grasped by the grasper and moved into the dilator (Fig. 8D). The cavity is dilated to remove the tissue from the body (Fig. 8E). As to claim 19, note that the tissue is retained in the leading end of the dilator (Fig. 8E). As to claim 20, Figure 8C shows the cannula being removed from the body with the dilator 27 remaining in the expanded position. As to claim 58, note the retainer 30 for restricting the dilator in the unexpanded position. The retainer is removed to allow the dilator to move to the expanded position (column 4, lines 40-42).

Claims 1, 5, 18, 19, 21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Richard (6,383,195). Richard shows a surgical extractor comprising a body 50 having a leading end, a trailing end, a longitudinal axis and a lumen between

the ends. The lumen includes a seal (column 5, lines 58-65) and a dilator 15 is located at the leading end of the body and is movable between an unexpanded position (Fig. 1) and an expanded position (Fig. 2). As to claim 5, the maximum cross-sectional dimension of the body is smaller than the expanded cross-sectional dimension of the dilator, as can be seen in Figure 2. As to claim 18, note that a cannula 40 is inserted into the body cavity and the dilator is inserted through the cannula. The leading end of the dilator is expanded and a grasper (forceps shown in Fig. 2) is inserted through the dilator. The tissue 30 is grasped by the grasper and moved into the dilator (Fig. 3). The cavity is dilated to remove the tissue from the body (column 3, lines 56-65). As to claim 19, note that the tissue is retained in the leading end of the dilator (Fig. 3). As to claim 21, note that fluid or other material may be suctioned from the material (column 3, lines 6-8). As to claim 23, note that the leading end of the dilator includes a draw cable 28 which is used to draw the leading end of the dilator closed. As to claim 24, the cannula is removed with the dilator in an expanded position.

Claims 35, 36, 38, 42, 45-48, 50 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu et al (2002/0068943). Chu shows a surgical extractor comprising a body 12 having a leading end, a trailing end, a longitudinal axis and a lumen 18 between the ends. A dilator 10 is located at the leading end of the body and is movable between an unexpanded position and an expanded position. The dilator has tissue-retaining protrusions 13 in the form of teeth (see Fig. 20E) spaced about the entire inner surface of the dilator. As to claims 42 and 45, the dilator includes a memory element 11a, 11b, 11c configured to expand the dilator from the unexpanded position

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(para. 0095). The memory elements are parallel to the longitudinal axis when the dilator is in the expanded position. As to claims 46 and 47, note paragraph 0096. As to claims 48 and 58, the body 12 is considered to be the retainer.

Claims 6, 7, 10, 17, 77, 78, 82-84, 86-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (6,099,550). Yoon shows a grasper 30 for grasping tissue comprising a shaft 36 having a trailing end, a leading end, and a lumen therebetween, at least two grasping surfaces 38, 40 at the leading end and a handle 44, 46 at the trailing end to operate the grasping surfaces. As to claim 78, the front wall 50 of housing 32 is considered a depth limiting protrusion because the instrument cannot be inserted into the body cavity any further than that wall. As to claim 83, note the ridges on the grasping surfaces shown in Figure 18. As to claim 84, note the seal 84 in Figure 10. As to claim 6, note that the instrument may be used to suction fluid (column 5, lines 26-29). As to claim 17, note that tissue may be removed from the cavity (column 8, lines 13-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (5,643,282) in view of Stevens (5,643,227). The seal of Kieturakis is not disclosed as being a two part seal. Stevens shows a two part seal wherein the first part 22a seals the lumen when the instrument is inserted into the lumen and the second part 22b seals the lumens when the instrument is removed from the lumen. This arrangement reduces leakage through the seal. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the body of Kieturakis with a two part seal, as taught by Stevens, in order to prevent leakage during the procedure.

Claims 8, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (5,843,017) in view of Zakko (5,527,274). Yoon does not disclose the use of MTBE to at least partially dissolve the tissue before removal. Zakko teaches that it is well known to use MTBE to dissolve gallstones without injury to the gallbladder (see "Background of the Invention"). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a step of treating the tissue of Yoon with MBTE, as taught by Zakko, if the tissue is to large to remove from the small passage into the body.

Claims 16, 31, 32, 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (5,843,017). Without a showing of criticality, the dimensions of the various parts of the instrument are considered to have been obvious design choices, to one of ordinary skill in the art, depending on the procedure being performed.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richard (6,383,195). Without a showing of criticality, the dimensions of the various parts of the instrument are considered to have been obvious design choices, to one of ordinary skill in the art, depending on the procedure being performed. Also, note column 9, lines 3-5.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al (2002/0068943). Without a showing of criticality, the dimensions of the various parts of the instrument are considered to have been obvious design choices, to one of ordinary skill in the art, depending on the procedure being performed. As to claim 59, Chu discloses that the retainer comprises a

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (5,643,282). Kieturakis only discloses that the retainer is made of a thin-walled plastic (column 3, line 65). The use of polyurethane to form this retainer is considered to have been an obvious design choice, particularly considering its widespread use in the medical field.

Claims 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (5,643,282) in view of Zakko (5,527,274). Kieturakis discloses a method for removing tissue from a body cavity comprising all the claimed steps except the use of MTBE to at least partially dissolve the tissue before removal. Zakko teaches that it is well known to use MTBE to dissolve gallstones without injury to the gallbladder (see "Background of the Invention"). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a step of treating the tissue of

Kieturakis with MBTE, as taught by Zakko, if the tissue is too large to remove from the small passage into the body.

Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heidmueller (5,281,230). Without a showing of criticality, the dimensions of the various parts of the instrument are considered to have been obvious design choices, to one of ordinary skill in the art, depending on the procedure being performed.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richard (6,383,195) in view of Heidmueller (5,281,230). Richard does not teach the step of suctioning bile or other material from a gallbladder. Heidmueller teaches a method of extracting a gallbladder wherein bile or other material is suctioned from the gallbladder (column 2, lines 22-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the instrument of Richard to remove the gallbladder and further include the step of suctioning bile or other tissue, in view of Heidmueller, in order to reduce the mass of the tissue being extracted.

Allowable Subject Matter

Claims 27-29, 37, 39-41, 43, 44, 60 and 89-92 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 51-57 and 61-72 are allowed.

Claims 12-14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 304 (page 14, lines 1-2). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 703-308-2701. The examiner can normally be reached on M-Th, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 703-308-0858. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Cary E O'Connor
Cary E. O'Connor
Primary Examiner
Art Unit 3732

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April 14, 2003